ISRCTN16444200 https://doi.org/10.1186/ISRCTN16444200

A randomised controlled trial to study the side effect profile and to establish measures of efficacy using photofrin or 5-aminolaevulinic acid (ALA) photodynamic therapy in the eradication of dysplasia in Barretts columnar lined oesophagus

Submission date
26/01/2006

Recruitment status
No longer recruiting

Registration date
07/02/2006

Overall study status
Completed

Last Edited
28/08/2013

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Version 3.1

Study information

Scientific Title

Study objectives
To determine whether photodynamic therapy for high grade dysplasia in Barrett's oesophagus using aminolaevulinic acid has less side effects than photofrin. To develop novel measures of efficacy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Berkshire Research Ethics Committee, 13/01/2006, ref: 05/Q1602/193

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
High grade dysplasia in Barrett's oesophagus

Interventions
Photodynamic therapy using 5-aminolaevulinic acid versus photofrin

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Aminolaevulinic Photofrin

Primary outcome(s)
1. Eradication of high grade dysplasia
2. Prevention of oesophageal cancer
3. Side effect profiles of different types of photodynamic therapy

Key secondary outcome(s)
1. Quality of life outcomes
2. Develop novel methods for treatment efficacy
3. Reversal of Barrett's oesophagus

Completion date
01/02/2009

Eligibility

Key inclusion criteria
1. Patients with high grade dysplasia in Barrett's oesophagus but without invasive cancer
2. Aged over 21

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Severe cardiovascular disease
2. Liver cirrhosis or seriously impaired hepatic or renal function
3. Depot antipsychotics
4. Concomitant chemoradiotherapy
5. Pregnancy
6. Porphyria
7. Previous photodynamic therapy

Date of first enrolment
01/02/2006

Date of final enrolment
01/02/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
National Medical Laser Centre
London
United Kingdom
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Sponsor information

Organisation
University College London (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Medical Laser Centre (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2013		Yes	No